

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 14875-159US1 C1-A0315P-US U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) <div style="font-size: 2em; font-weight: bold; text-align: center;">10/575192</div>
INTERNATIONAL APPLICATION NO. PCT/JP2004/014935	INTERNATIONAL FILING DATE 8 October 2004	PRIORITY DATE CLAIMED 9 October 2003
TITLE OF INVENTION Highly Concentrated Stabilized IgM Solution		
APPLICANT(S) FOR DO/EO/US Tomoyuki Igawa and Yasuo Sekimori		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 C.F.R. 1.76.
15. ☒ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☒ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 C.F.R. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

CERTIFICATE OF MAILING BY EXPRESS MAIL
 Express Mail Label No. EV 664069135 US
 Date of Deposit: April 7, 2006

SUBSTITUTE PTO-1390

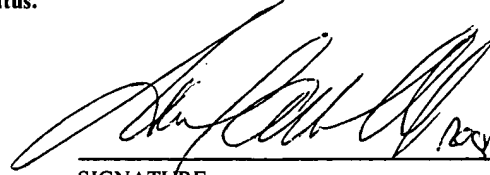
U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/575192		PCT/JP2004/014935		14875-159US1	
20. Other items or information: Sequence Listing Statement under 37 CFR § 1.821(f) Sequence Listing paper copy (11 pages) International Search Report Substitute Specification (marked up version) Statement of Substitute Specification under 37 CFR § 1.125					
The following fees have been submitted				CALCULATIONS PTO USE ONLY	
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.192(a))				\$300	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))				\$200.00	
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by the IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)				\$0	
All other situations				\$200	
23. <input type="checkbox"/> Search fee (37 CFR 1.92(b))				\$400.00	
If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)				\$0	
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority				\$100	
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB				\$400	
All other situations				\$500	
Total of 21, 22 and 23 =				\$900.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing filed in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
-100 =	/50 =		X \$250	\$0.00	
Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 C.F.R. 1.492(h)).				\$0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	35 - 20 =	15	x \$50	\$750.00	
Independent Claims	3 - 3 =	0	x \$200	\$0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ \$360	\$0.00
TOTAL OF ABOVE CALCULATIONS =				\$1,650.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 C.F.R. 1.27. Fees above are reduced by 1/2.				\$0.00	
SUBTOTAL =				\$1,650.00	
Processing fee of \$130 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 C.F.R. 1.492(i))				+	\$0.00
TOTAL NATIONAL FEE =				\$1,650.00	
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property				+	\$0.00
TOTAL FEES ENCLOSED =				\$1,650.00	
				Amount to be refunded:	\$0.00
				Amount to be charged:	\$0.00

- a. ☒ A check in the amount of \$1,650.00 to cover the above fees is enclosed. **IAP9 Rec'd PCT/PTO 07 APR 2000**
- b. ☐ Please charge my Deposit Account No. 06-1050 in the amount of \$0.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-1050. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 C.F.R. 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

PTO Customer No: 26161

 1250030125
SIGNATURE

Janis K. Fraser, Ph.D., J.D.

NAME

34,819

REGISTRATION NUMBER

10/575192

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Igawa et al. Art Unit : Unknown
Serial No. : To Be Assigned Examiner : Unknown
Filed : Herewith
Title : HIGHLY CONCENTRATED STABILIZED IGM SOLUTION

MAIL STOP PCT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

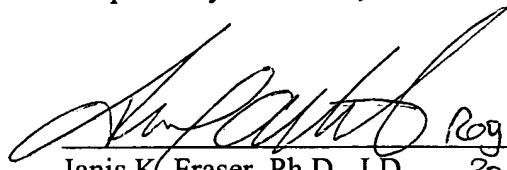
STATEMENT OF SUBSTITUTE SPECIFICATION UNDER 37 CFR § 1.125

Pursuant to 37 CFR § 1.125, Applicants submit a substitute specification encompassing changes being made to the original specification. The changes to the specification add a cross-reference to related applications and correct obvious errors and omissions in the original. No new matter is introduced by the attached substitute specification, and Applicants request its entry.

Also submitted herewith is a marked-up version showing the changes that have been made.

Respectfully submitted,

Date: 4-7-6


Janis K. Fraser, Ph.D., J.D.
Reg. No. 34,819

Reg No
30,125

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April 7, 2006
Date of Deposit